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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,618	04/19/2001	Brett T. Haarala	10123/01101	3578

7590 03/24/2006  
Fay Kaplun & Marcin, LLP  
150 Broadway  
Suite 702  
New York, NY 10038

EXAMINER

KEASEL, ERIC S

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/838,618		HAARALA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Eric Keasel		3754	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 and 47-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-46 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. In view of the appeal brief filed on January 3, 2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:



**MICHAEL MAR**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**

### *Election/Restrictions*

2. Claims 1-42 and 47-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 25, 2002.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 43, 44 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5,752,970).

Yoon discloses a medical device (20) having an elongate catheter (22) with an external surface and an internal surface defining an internal lumen (Figure 3) and having a compound slit located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (unlabelled Figure 2). The slit of Yoon is biased closed and would inherently open due to difference in pressure between the lumen and the ambient. The slit of Yoon is also configured to inherently allow the flaps to flex into the lumen when the ambient pressure exceeds the pressure inside the lumen.

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6. Claims 43, 44 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Eaton (US 3,303,847).

Eaton discloses a medical device having an elongate catheter (5) with an external surface and an internal surface defining an internal lumen and having a compound slit (8, 9) located at a generally hemispherical distal end portion (6) of the catheter and extending from the external surface to the internal surface (see Fig. 4). The slit of Eaton is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Eaton is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen.

7. Claims 43, 44, 46, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson (US 2,063,424).

Ferguson discloses a medical device having an elongate catheter with an external surface and an internal surface defining an internal lumen and having a compound slit (3, 4, 5) located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (see Fig. 1). The slit of Ferguson is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Ferguson is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen.

8. Claims 43, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi (US 2,063,424).

Yamauchi discloses a medical device having an elongate catheter with an external surface and an internal surface defining an internal lumen and having a compound slit (6) located at a

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generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (see Fig. 3). The slit of Yamauchi is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Yamauchi is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eaton in view of Engelson et al. (US Patent Number 5,798,018).

Eaton fails to disclose the collar. Engelson et al. disclose a collar (130) used on a similar catheter. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to have used the collar of Engelson et al. with the catheter of Eaton so that the catheter can be radiographed visually as taught by Engelson et al.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Engelson et al. (US Patent Number 5,798,018).

Yoon fails to disclose the collar. Engelson et al. disclose a collar (130) used on a similar catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the collar of Engelson et al. with the catheter of Yoon so that the catheter can be radiographed visually as taught by Engelson et al.

### ***Response to Arguments***

12. Applicant's arguments filed January 3, 2006 have been fully considered but they are not persuasive. The examiner has provided a number of other anticipatory references that should convince applicant that resilient check valves inherently open due to a pressure difference on either side of the check valve. Even though Yoon discloses that a rigid bar can also open the check valve at the end of the catheter, this does not change the fact that the check valve will open under a fluid pressure difference.

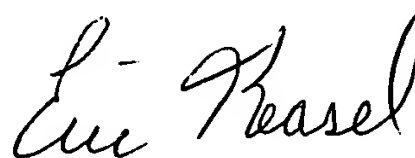
### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Keasel whose telephone number is (571) 272-4929. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mar can be reached on (571) 272-4906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Eric Keasel". The signature is fluid and cursive, with the first name "Eric" and last name "Keasel" clearly distinguishable.

Eric Keasel  
Primary Examiner  
Art Unit 3754